Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13463

0 - FRONT

[redacted]

COMPLAINT/INJURY REPORT

Complaint Number: [redacted]

Date of Complaint: 1/26/99 (13463)

1. COMPLAINT INFORMATION

a. Form of complaint: ☐ Telephone ☐ Visit ☐ Letter ☐ Other

b. Source of complaint: ☐ Consumer ☐ Trade Source ☐ Government ☐ Other

2. INJURED PARTY AND/OR COMPLAINANT INFORMATION

a. Injured Party (name and address):

[redacted]

Phone (hm & wk): [redacted]

b. Complainant (name and address):

Same

Phone (hm & wk):

c. Age: 52 d. Sex: F e. Region: [redacted] f. County: [redacted]

3. INJURY OR ILLNESS RESULTED

☐ Yes ☐ No

a. Symptoms: Date/Time of Onset:

1. ☐ Vomiting
2. ☐ Nausea
3. ☐ Diarrhea
4. ☐ Fever
5. ☐ Skin Irr.
6. ☐ Eye Irr.
7. ☐ Headache
8. ☒ Other Chest Pain

b. Attending Physician ☒ Yes ☐ No (if yes, then name and address)

Dr [redacted] Cardiologist

c. Attending Hospital ☒ Yes ☐ No (if yes, then name and address)

[redacted]

Phone

4. PRODUCT AND LABELING (as applicable)

a. Product Name:
c. Type Package:
e. Exp./Use Date:
g. Date Purchased:
i. Sample #:

b. Product Code:
d. Pkg Code/Serial #:
f. Date Used:
h. Amt. Remaining:

5. MANUFACTURER /DISTRIBUTOR INFORMATION

a. Manufacturer (name and address)

Metabolife

Phone:

b. Distributor/Retailer (name and address)

[redacted]

Phone:

6. COMPLAINT OR INJURY

a. Nature of Complaint/Injury

☐ Adulterated ☒ Illness/Injury ☐ Tampering
☐ Sanitation ☐ Misbranded ☐ Other

b. Valid ☐ Yes ☐ No

c. Follow-up ☐ Yes ☐ No

d. Notice ☐ Yes ☐ No ____ Days

OFFICE USE ONLY

ASSIGNED TO INVEST.: [redacted]

DIVISION / BRANCH: [redacted]

INJURY CLASS [redacted]

REVIEWER'S INITIALS: [redacted]

DATE REVIEWED: 2/15/99

e. Description of Complaint/Injury:

Purchased product on the 15th - On Saturday the 16th around 11:30am she took 1 tablet - as fixing lunch felt a little jittery Around 5pm took another tablet (before dinner) That evening around 11pm - felt sharp pain in your chest (side of the heart) and the left arm. Sat down - calmed. Continued to feel pain in the chest. Husband recommended that she sit down and have a glass of wine (calm her down). Got up Sunday morning (did not take anymore product) - then around 3pm felt more chest pains - husband called [redacted] and the nurse called back and told her to come into the hospital immediately. In the hospital - ran EKG and blood work and other test (enzymes elevated). Then the cardiologist came in and he admitted her - spent the entire evening in the hospital - ran a stress test on Monday morning. Was on a blood thiner in the IV while in the hospital. Return to see doctor next week for follow up. Also called radio station - they were shocked and they still continue to advertise Metabolife. - Asthmatic — Seravent, Promocourt, Claritin D (cardiologist told her to get off of the product). Said she was reasonably healthy.

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7. DISPOSITION: Closed - interviewed injured party, obtained medical records.

8. REFERRED TO: N/A

9. DATE REFERRED: N/A

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EIR **1/26/99**

COMPLAINT # [redacted]

[redacted]

[redacted]: **NONE**

SUMMARY OF FINDINGS:

This was a complaint inspection of a dietary supplement, conducted by [redacted] On 1/26/99, the [redacted] received a telephone complaint from Ms. [redacted] of [redacted] regarding a nutritional supplement. Ms. [redacted] stated that on 1/16/99 she took one Metabolife tablet before lunch. She stated she felt jittery after taking the tablet. Around 5:00pm, she took another tablet before dinner. The same evening around 11:00pm, she felt a sharp pain in her chest and her left arm. Ms. [redacted] stated the next morning (1/17/99) she did not take any additional tablets, but that approximately 3:00pm she began to feel more chest pains. After contacting [redacted] her husband took her to the emergency room. Ms. [redacted] stated the physicians ran several tests on her including bloodwork, a stress test, and an electrocardiogram. Ms [redacted] stated she was released from the hospital the next day (1/18/99).

On 1/26/99 I went to Ms. [redacted] place of business to have her sign an Authorization For Medical Records Disclosure (see attachment). While interviewing Ms. [redacted] she indicated she took the supplement to lose weight. I attempted to sample the remaining tablets of Metabolife purchased by Ms. [redacted] however, on 1/19/99 she returned the unused portion to the Metabolife kiosk in [redacted] where she purchased it.

On 1/26/99 I went to the Metabolife kiosk to obtain the returned product. The Metabolife representative (name unknown) stated returned products are immediately sent back to the manufacturer for credit. He stated any return that occurred on 1/19/99 would not be available. I obtained promotional material from Metabolife (see attachment).

Also on 1/26/99 I went to [redacted] to obtain Ms. [redacted] medical records for her visit on 1/17-18/99. The following day the records were made available by the hospital (see attachment).

Attachments to this report include Authorization For Medical Records Disclosure, Metabolife promotional literature, medical records for Ms. [redacted] and a copy of complaint #100048.

[redacted]

[redacted]

INVESTIGATOR

[redacted]

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